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CYR & ASSOCIATES, P.A.
605 U.S. Highway 169
Suite 300
Plymouth, MN 55441

EXAMINER	
YU, MISOOK	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS DAG HORN and SANDRA MARCHESE JOHNSON

Appeal 2007-3908
Application 10/081,185
Technology Center 1600

Decided: January 23, 2008

Before ERIC GRIMES, LORA M. GREEN, and NANCY J. LINCK, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1, 4-7, 33, 36, 37, and 48-51. We have jurisdiction under 35 U.S.C. § 6(b). Claim 1 is representative of the claims on appeal, and reads as follows:

1. A pharmaceutical composition comprising at least two antigens and a pharmaceutically acceptable carrier, wherein

each of said antigens induces or is capable of inducing a cutaneous delayed type hypersensitivity response in a mammalian subject;

the composition is capable of treating a benign epithelial tumor caused by a papilloma virus in a mammalian subject; and

one of the two antigens is a bacterial antigen and the other is a candida antigen.

We affirm.

ISSUE

Appellants contend that the Declaration of Thomas Dag Horn submitted under 37 C.F.R. § 1.132 removes Bostwick as a reference.

The Examiner contends that the Declaration does not establish conception of the claimed composition of a bacterial and candida antigen.

Thus, the issue on Appeal is: Is the Declaration of Thomas Dag Horn submitted under 37 C.F.R. § 1.131 (Horn Declaration) sufficient to remove Bostwick as a reference?

FACTS

The Examiner rejected claims 1, 4-7, 33, 36, and 48-51 under 35 U.S.C. § 102(e) as being anticipated by Bostwick[1] (Answer[2] 3-4). The Examiner also rejected claims 1, 4-7, 15, 33, 36, 37, and 48-51 under 35

[1] Bostwick, Pub. No. US 2002/0009429 A1, published January 24, 2002, filed January 29, 1999.

[2] All references to the Answer are to the Examiner's Answer mailed March 13, 2007.

U.S.C. § 103(a) as being obvious over the combination of Bostwick as combined with the CANDIN® package insert[3] (*id.* at 4-5).

Appellants do not argue the merits of the rejection (Br.[4] 5, 18). Rather, Appellants assert that the Horn Declaration "establishes possession of the invention of administering antigens causing a delayed type hypersensitivity response to epithelial tumors to treat the tumors, including antigens unrelated to the causative agent of the epithelial tumor, before the effective date of Bostwick." (*Id.* at 5 (emphasis removed)).

The Declaration was signed by one of the two inventors, Thomas Dag Horn. In addition, the Declaration does not address the country in which the activities used as the evidence relied upon to establish reduction to practice, either actual or constructive, took place.

The Declaration states that "I conceived the claimed invention of U.S. Patent Application Serial No. 10/081,185, before the filing date of Bostwick of January 29, 1999, and diligently pursued development of the invention from my conception of the invention before January 29, 1999, until the filing of U.S. Patent Application Serial No. 09/344,357 on June 25, 1999." (Horn Declaration, ¶ 3.)

The Declaration states further that:

> My conception of the claimed invention and diligence in pursuing it is evidenced by the attached letter from Fred H. Faas, M.D., which is dated before January 29, 1999 (date redacted). The letter is an approval letter to proceed with use of mumps and candida intradermal skin test antigens to treat human patients afflicted with Verruca vulgaris (common warts). The letter refers to the use of mumps and candida

[3] Submitted with the IDS of March 14, 2003, Reference A12.
[4] All references to the Brief are to the Appellants' Amended Brief on Appeal, date stamped October 10, 2006.

> antigens. At the time of the letter, I also believed that any antigen that induced a cutaneous delayed-type hypersensitivity response, including bacterial antigens, would successfully treat warts and other benign epithelial tumors. At the time of this letter from Dr. Faas and at the time of submitting the protocol that the letter refers to, I planned to combine two or more antigens in a single composition to be administered for treatment of warts and other epithelial tumors. The compositions with two or more antigens that I had conceived and planned to use included compositions containing mumps and candida antigens, as well as compositions containing candida and bacterial antigens.

(Horn Declaration, ¶ 4.)

The only evidence submitted with the Horn Declaration is a letter signed by Fred H. Faas, M.D. The only reference to the claimed invention is the "Title," which is "Application of Mumps and Candida Intradermal Skin Tests in Patients with Verruca Vulgaris."

PRINCIPLES OF LAW

37 C.F.R. § 1.131 states, in relevant part:

> (a) When any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the party qualified under §§ 1.42, 1.43, or 1.47, may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based. The effective date of a U.S. patent, U.S. patent application publication, or international application publication under PCT Article 21(2) is the earlier of its publication date or date that it is effective as a reference under 35 U.S.C. 102(e). Prior invention may not be established under this section in any country other than the United States, a NAFTA country, or a WTO member country. Prior invention may not be established

> under this section before December 8, 1993, in a NAFTA country other than the United States, or before January 1, 1996, in a WTO member country other than a NAFTA country.. . .
> (b) The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence must be satisfactorily explained

ANALYSIS

We find the Horn Declaration to be deficient in several regards.

First, it was signed only by one of the inventors, Thomas Dag Horn. Rule 131 requires the Declaration to be signed by all of the inventors. The Declaration was not signed by the second inventor of record, Sandra Marchese Johnson, nor have Appellants made a showing under 37 C.F.R. §§ 1.42, 1.43, or 1.47.

Second, the Declaration does not establish a reduction to practice, either actual or constructive, of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Bostwick reference.

Third, even if we were to decide the merits of the Declaration, it would still be insufficient to antedate the Bostwick reference. The letter submitted as evidence only refers to the application of mumps (a viral antigen) and candida intradermal skin tests in patients with Verruca vulgaris. Thus, the composition of the evidence provided does not fall within the

claimed composition, which requires a bacterial antigen and a candida antigen.

If Appellants are using the letter as evidence of conception of the invention, the Declaration fails as there is no evidence provided of due diligence from prior to the date of the Bostwick reference to a subsequent reduction to practice or to the filing of the application.

If Appellants are using the letter as evidence of reduction to practice, the Declaration fails as the composition that was reduced to practice is outside the scope of the claimed composition, and there is no evidence provided showing that the differences between the claimed invention and the showing in the Declaration would have been obvious to one of ordinary skill in the art in view of the evidence in the Declaration.

CONCLUSION

Because we find that the Horn Declaration, submitted under 37 C.F.R. § 1.131, is insufficient to antedate the Bostwick reference, the rejection of claims 1, 4-7, 33, 36, and 48-51 under 35 U.S.C. § 102(e) as being anticipated by Bostwick, and the rejection of claims 1, 4-7, 15, 33, 36, 37, and 48-51 under 35 U.S.C. § 103(a) as being obvious over the combination of Bostwick as combined with the CANDIN® package insert, are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

CYR & ASSOCIATES, P.A.
605 U.S. Highway 169
Suite 300
Plymouth MN 55441